



## PHARMACY POLICY STATEMENT Ohio Medicaid

DRUG NAME	Vyondys 53 (golodirsen)
BILLING CODE	J1429 (1 unit = 10 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT – see dosage allowed
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Vyondys 53 (golodirsen) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### DUCHENNE MUSCULAR DYSTROPHY (DMD)

For **initial** authorization:

1. Member has a diagnosis of DMD with confirmed mutation of DMD gene that is amenable to exon 53 skipping (genetic testing results required); AND
2. Medication is being prescribed by or in consultation with a DMD specialist (i.e., neurologist); AND
3. Member is currently stable on corticosteroid for at least 3 months prior to starting therapy, unless not tolerated or contraindicated; AND
4. Member has had a 90-day trial and failure of, or contraindication to Viltepso; AND
5. Chart notes have been provided to show that the member is able to walk independently without assistive devices.
6. **Dosage allowed:** 30 mg per kg of body weight once weekly.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show stability or slowed rate of decline of the member's motor function compared to baseline; AND
2. Chart notes confirm that member remains able to walk independently without assistive devices.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.***

**CareSource considers Vyondys 53 (golodirsen) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
1/21/2020	New policy for Vyondys 53 created.
06/17/2020	Length of corticosteroid trial specified to be at least 3 months. Age requirement removed.
01/14/2021	Added prescriber requirement. Simplified ambulatory requirement. Added requirement of stability or slowed rate of decline of motor function in reauth section. Added a trial of Viltepso.



References:

1. Vyondys 53 [Package Insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; August 2020.
2. Sarepta Therapeutics, Inc. Phase I/II Study of SRP-4053 in DMD Patients. NLM Identifier: NCT02310906.
3. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in *Lancet Neurol*. 2018 Apr 4;:]. *Lancet Neurol*. 2018;17(3):251-267.
4. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(5):465-472.
5. Frank DE, Schnell FJ, Akana C, et al. Increased dystrophin production with golodirsen in patients with Duchenne muscular dystrophy. *Neurology*. 2020;94(21):e2270-e2282. doi:10.1212/WNL.0000000000009233

Effective date: 07/01/2021

Revised date: 01/14/2021